HEURIVED
CENTRAL FAX CENTER

MAR 2 6 2008

LAW OFFICES OF

FAY KAPLUN & MARCIN, LLP

INTELLECTUAL PROPERTY LAW

150 BROADWAY, SUITE 702 NEW YORK, NEW YORK 10038 PHONE: (212) 619-6000 FAX: (212) 208-6819 WWW.FKMIPLAW.COM

FACSIMILE COVER SHEET

FAX NO :

(571) 273-8300

TO

Commissioner for Patents

Mail Stop: Appeal Brief-Patents

FROM

Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP

DATE

March 6, 2008

SUBJECT

U.S. Patent Appln. Serial No. 10/530,087

for Device for Bone Fixation
Our Ref.: 10139/04101

NUMBER OF PAGES INCLUDING COVER: 23

MESSAGE:

Please see attached.

Thank you.

IF ANY PAGES WERE NOT RECEIVED OR ARE ILLEGIBLE, PLEASE CALL (212) 619-6000 AS SOON AS POSSIBLE

The information contained in this facsimile message is attorney privileged and confidential information intended only for the use of the individual or entity named above. If the reader of this message is not the intended recipient or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us by telephone, and return the original message to us at the above address via the U.S. Postal Service. We will reimburse any costs you incur in notifying us and returning the message to us. Thank you.

Attorney Docket No. 10139/04101 (00271-06PUS1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)

Munro et al.

Serial No.

10/530,087

Filed

January 30, 2006

For

Device for Bone Fixation

Group Art Unit

3733

Confirmation No.

7522

Examiner

Nicholas W. Woodall

Mail Stop: Appeal Brief-Patents Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

Certificate of Facsimile/Mailing
hereby certify that this correspondence is b

I hereby certify that this correspondence is being transmitted via facsimile or First Class Mail addressed to:

Mail Stop: Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 2213-1450 (571) 273-8300

Dale: March 26, 200

GENTRAL FAX CENTER

MAR 2 6 2008

TRANSMITTAL

In response to the Notification of Non-Compliant Appeal Brief mailed on March 20, 2008, transmitted herewith please find a revised Appeal Brief for filing in the above-identified application. No fees are believed to be required. However, the Commissioner is hereby authorized to charge the Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492 for any additional required fees. A copy of this paper is enclosed for that purpose.

Dated: March 26, 2008

Respectfully submitted,

Oleg F. Kaplun (Reg. No. 45,55)

Fay Kaplun & Marcin, LLP 150 Broadway, Suite 702 New York, NY 10038

Tel: (212)619-6000 Fax: (212) 619-0276 Attorney Docket No. 10139/04101 (00271-06PUS1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)

Munro et al.

RECEIVED

CENTRAL FAX CENTER

Serial No.

10/530,087

MAR 2 6 2008

Filed

January 30, 2006

For

Device for Bone Fixation

Group Art Unit

3733

Confirmation No.

7522

Examiner

Nicholas W. Woodall

Mail Stop: Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Certificate of Facsimile/Mailing
I hereby certify that this correspondence is being

transmitted via facsimile or First Class Mail

addressed to:

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450

Alexandria, VA 2213-1450 (571) 273-8300

Dale:

Date: March 6, 2008

TRANSMITTAL

In response to the Notification of Non-Compliant Appeal Brief mailed on March 20, 2008, transmitted herewith please find a revised Appeal Brief for filing in the above-identified application. No fees are believed to be required. However, the Commissioner is hereby authorized to charge the Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492 for any additional required fees. A copy of this paper is enclosed for that purpose.

Dated: March 26, 2008

Respectfully submitted,

Oleg F. Kaplun (Reg. No. 45,559

Fay Kaplun & Marcin, LLP 150 Broadway, Suite 702

New York, NY 10038 Tel: (212)619-6000

Fax: (212) 619-0276

RECEIVED CENTRAL FAX CENTER

MAR 2 6 2008 PATENT

Attorney Docket No.: 10139 - 04101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	
Munro et al.	
Serial No.: 10/530,087	Group Art Unit: 3733
Filed: January 30, 2006	Examiner: Nicholas W. Woodall
For: DEVICE FOR BONE FIXATION)	Board of Patent Appeals and Interferences

Mail Stop: Appeal Brief - Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In response to the Notification of Non-Compliant Appeal Brief dates March 20, 2008 and in support of the Notice of Appeal filed January 11, 2008, and pursuant to 37 C.F.R. § 41.37, Appellants present this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 and 4 - 21 in the Final Office Action dated September 17, 2007. The appealed claims are set forth in the attached Claims Appendix.

Group Art Unit: 3733 Attorney Docket No.: 10139 - 04101

1. Real Party in Interest

This application is assigned to Synthes (U.S.A.), the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1 and 4 - 21 stand rejected in the Final Office Action. Claims 2 and 3 have been canceled. The final rejection of claims 1 and 4 - 21 is being appealed.

4. Status of Amendments .

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention describes, as recited in claim 1, a bone fixation device comprising an intramedullary pin 1 having a longitudinal axis 17, a proximal end 3 and a distal tip 2 configured and dimensioned for insertion into a medullary canal of a bone. (See Specification, ¶ [0021]; Figs. 1 - 2). Claim 1 also recites that the intramedullary pin 1 has a total length with proximal and distal halves 7 and 4 where the proximal half 7 includes at least one borehole 6 passing through the intramedullary pin 1 transverse to the longitudinal axis 17, the at least one borehole 6 defining a transverse borehole axis 18. (Id. at ¶ [0021], [0022]; Figs. 1, 2, 4). Claim 1 further recites a bone plate 10 disposed at the proximal end 3 of the intramedullary pin 1, the bone plate 10 having a length L extending toward the distal tip 2 of the intramedullary pin 1 and adapted to lie in contact with the greater trochanter. (Id. at ¶ [0011], [0021]; Figs. 1, 2, 4). Claim 1 further recites that the length of the bone plate 10 ends proximally above the borehole 6 in the intramedullary pin 1. (Id. at ¶ [0021]; Figs. 1, 2, 4). Claim I further recites that the bone plate 10 includes an angled tab 22 configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin 1 taken orthogonally to the intramedullary pin's longitudinal axis 17 and enclosing an angle β relative to a plane defined by the transverse borehole axis 18 and the intramedullary pin's longitudinal axis 17, where angle β is between 0° and $+100^{\circ}$ or between 0° and -100° . (Id. at ¶ [0012], [0022]; Figs. 1, 2, 4).

Attorney Docket No.: 10139 - 04101

Claim 18 recites a bone fixation device comprising an intramedullary pin 1 having a longitudinal axis 17, a proximal end 3 and a distal end configured and dimensioned for insertion into a medullary canal of a bone. (Id. at, ¶ [0021]; Figs. 1 - 2). Claim 18 also recites that the intramedullary pin 1 has a total length with proximal and distal halves 7 and 4, respectively where the proximal half 7 includes at least one borehole 6 passing through the intramedullary pin 1 transverse to the longitudinal axis 17, the at least one borehole 6 defining a transverse borehole axis 18. (Id. at ¶ [0021], [0022]; Figs. 1, 2, 4). Claim 18 further recites a bone plate 10 disposed at the proximal end 3 of the intramedullary pin 1, the bone plate 10 having an angled tab 22 with a pair of petals 23, 24 extending toward the distal end of the intramedullary pin 1 and adapted to lie in contact with the greater trochanter. (Id. at ¶ [0021], [0022], Figs. 1, 2, 4). Claim 18 further recites that the angled tab 22 does not extend past the borehole 6 in the intramedullary pin 1, wherein the angled tab 22 is configured and dimensioned to have a center of gravity lying on a radius 21 of a cross-sectional area 19 of the intramedullary pin 1 taken orthogonally to the intramedullary pin's longitudinal axis 17 and enclosing an angle β relative to a plane defined by the transverse borehole axis 18 and the intramedullary pin's longitudinal axis 17, where angle β is between 0° and $+100^{\circ}$ or between 0° and -100° . (Id. at ¶ [0012], [0022]; Figs. 1, 2, 4).

Claim 21 recites a bone fixation device comprising an intramedullary pin 1 having a longitudinal axis 17, a proximal end 3 and a distal tip 3 configured and dimensioned for insertion into a medullary canal of a bone. (Id. at, ¶ [0021]; Figs. 1 - 2). Claim 21 also recites that the intramedullary pin 1 has a total length with proximal and distal halves 7 and 4, respectively where the proximal half 7 includes at least one borehole 6 passing through the intramedullary pin 1 transverse to the longitudinal axis 17, the at least one borehole 6 defining a transverse borehole axis 18. (Id. at ¶ [0021], [0022]; Figs. 1, 2, 4). Claim 21 further recites a bone plate 10 disposed at the proximal end 3 of the intramedullary pin 1, the bone plate 10 having a length L extending toward the distal tip 3 of the intramedullary pin 1 and adapted to lie in contact with the greater trochanter. (Id. at ¶ [0011], [0021], Figs. 1, 2, 4). Claim 21 further recites that the length L of the plate 10 ends proximally above the borehole 6 in the intramedullary pin 1. (Id. at ¶ [0021]; Figs. 1, 2, 4). Claim 21 also recites that the bone plate 10 includes an angled tab 22 with a center of gravity, the angled tab 22 configured and dimensioned such that a first plane defined by the center of gravity and the longitudinal axis 17 intersects a second plane defined by the transverse borehole axis 18 and the longitudinal axis 17 at an angle of between 0° and $+100^{\circ}$. (Id. at ¶ [0012], [0022]; Figs. 1, 2, 4).

Attorney Docket No.: 10139 - 04101

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1, 7, 9, 13 and 21 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Chemello (U.S. Patent No. 6,077,264).
- II. Whether claims 6 and 16 are unpatentable under 35 U.S.C. § 103(a) as obvious over Chemello.
- III. Whether claims 1, 4-8, 13 and 16 are unpatentable under 35 U.S.C. § 103(a) as obvious over Stedtfield (Patent No. DE 198 29 228 C1) in view of Chemello.
- IV. Whether claim 14 is unpatentable under 35 U.S.C. § 103(a) as obvious over Stedtfeld in view of Chemello in further view of Pennig (U.S. Patent No. 5,356,413).
- V. Whether claim 18 is unpatentable under 35 U.S.C. § 103(a) as obvious over Stedtfeld in view of Chemello in further view of Seidel (U.S. Patent No. 4,858,602).
- VI. Whether claims 17, 19 and 20 are unpatentable under 35 U.S.C. § 103(a) as obvious over Stedtfeld in view of Chemello in further view of Pennig.
- VII. Whether claims 1, 9, 11 and 12 are unpatentable under 35 U.S.C. § 103(a) as obvious over Aginsky (U.S. Patent No. 4,227,518) in view of Chemello.

7. Argument

I. The Rejection of Claims 1, 7, 9, 13 and 21 Under 35 U.S.C. § 102(b) as Anticipated by Chemello Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 7, 9, 13 and 21 were rejected under 35 U.S.C. 102(b) as anticipated by Chemello. (See 9/17/07 Office Action, pp. 2 - 3). In support of the rejection, the Examiner stated that Chemello teaches all of the limitations of claim 1, not referencing any particular elements of Chemello therein. (*Id.*). The Examiner further stated that the limitation of an angular tab in claim 1 is a functional limitation and accordingly, that Chemello need only disclose a structural element capable of performing the function of the angled tab. (*See* 12/3/07 Advisory Action, p. 2).

Attorney Docket No.: 10139 - 04101

B. Chemello Does Not Show or Suggest an Angled Tab as Recited in Claim 1

Claim 1 recites a bone fixation device comprising "an intramedullary pin having a longitudinal axis, a proximal end, and a distal tip configured and dimensioned for insertion into a medullary canal of a bone," wherein the intramedullary pin has proximal and distal halves with the proximal half including "at least one borehole passing through the intramedullary pin transverse to the longitudinal axis, the at least one borehole defining a transverse borehole axis" and "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter, wherein the length of the plate ends proximally above the borehole in the intramedullary pin and wherein the bone plate includes an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and $+100^{\circ}$ or between 0° and $+100^{\circ}$."

It is respectfully submitted that Chemello fails to teach or suggest "an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100," as recited in claim 1. The Examiner has further affirmed the above and stated that the Chemello device is "capable of being dimensioned wherein the center of gravity of the tab lies on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the longitudinal axis of the pin," thereby indicating that the Chemello device would have to be modified achieve the limitations of claims 1 and 21. (See 9/17/07 Office Action, p. 3). The Examiner goes on to recite that "it would be an obvious matter of design choice, since it has been held that where the general conditions of a claim are disclosed in the prior art, i.e. the ranges from 0 to 100 degrees or from 0 to -100 degrees, discovering the optimum or workable ranges, i.e. the ranges from 40 to 50 degrees or -40 to -50 degrees, involves only routine skill in the art," thereby further stressing the fact that Chemello fails to illustrate or describe elements recited in claims 1 and 21.

Attorney Docket No.: 10139 - 04101

(See 9/17/07 Office Action, p. 11). It is hereby noted, on account of the aforementioned language explicitly noting that the Chemello prior art reference must be modified in order to meet the limitations of claim 1, that a 35 U.S.C. § 102(b) rejection is improper and can not be upheld in this case. In response, the Examiner stated that the aforementioned limitation is a functional limitation and therefore, the prior art cited needs only to be capable of performing the indicated function. (See 12/3/07 Advisory Action, p. 2).

However, it is submitted that the limitation of "an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100," as recited in claim 1 is not a functional limitation but rather, a structural limitation intended to define the architecture of the angled tab. Specifically, the angled tab must be dimensioned so that the center of gravity is placed within an angle β of the transverse borehole axis (i.e., the center of gravity must fall on a select portion of the angled tab so that when placed over the greater trochanter, the center of gravity lies within \pm 100° of the transverse borehole axis). Were the angled tab structured differently, the center of gravity would fall out of the desired β range.

Thus, the recitation of "an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100," in claim 1 is structural and not functional.

It is respectfully submitted that Chemello fails to show or suggest this limitation and claim 1 is allowable over Chemello - under both the anticipation and obviousness standards and withdrawal of this rejection is requested. For the same reasons it is requested that the 35 U.S.C. § 102(b) rejection of dependent claims 7, 9 and 13 be withdrawn.

It is further noted that the Chemello device is incapable of being modified to overcome the limitations of claim 1. Specifically, Chemello fails to teach or suggest "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter," as recited in claim 1. Chemello makes no disclosure in this regard and rather, teaches only that the lip 91 connected at a proximal end to the screw 2, lies over the bone 8, making no reference

Attorney Docket No.: 10139 - 04101

to the location of the lip 91 relative to the greater trochanter. (See Chemello, col. 4, ll. 4 - 22). The drawings of Chemello, however, clearly indicate that the lip 91 is formed to lie over a portion of the bone abutting the intertrochanteric line of the thigh bone. (See Chemello, Figs. 2, 4a, 4). Specifically, the embodiments of Figs. 4a and 4, which show the anterior surface of the right femur, clearly depict the lip 91 seated over a portion of the anterior surface, spaced apart from the greater trochanter on the lateral wall of the bone. As further shown in the lateral view of Fig. 2 of Chemello, the nail object of Chemello juts out of the bone at a position below the greater trochanter and is therefore incapable of "[lying] in contact with the greater trochanter," as recited in claim 1. It is respectfully submitted that the 102(b) rejection of claim 1 is therefore not allowable for at least this additional reason.

Furthermore, it is submitted that Chemello teaches away from a nail object with a lip 91 made to "lie in contact with the greater trochanter," as recited in claim 1. Specifically, the Chemello device is directed to "a nail that can be easily removed from the bone inner cavity when this is necessary for any reason whatsoever." (See Chemello, col. 1, ll. 51 - 53). Accordingly, Chemello notes that the nail object is to reside within the bone inner cavity (i.e., the medullary cavity) which is housed in the shaft of the femur between the two epiphyses of the femur, as known to those skilled in the art. It is for this reason that Chemello designs the nail object to project out of the femur from an end portion of the medullary cavity, as shown in Fig. 2. It is submitted that modifying the Chemello device so that the nail object contacts the greater trochanter at a proximal end would be detrimental to the functioning of the device as it would reduce the ease of removal of the nail from "the bone inner cavity" by forcing the nail object into an additional layer of the bone (i.e., the spongy bone of the epiphysis) which would only complicate removal from the bone, as would be understood by those skilled in the art.

It is therefore submitted that Chemello fails to teach or suggest a "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter," as recited in claim 1 and rather, teaches away from this limitation. Still further, it is submitted that there would have been no motivation to have modified the Chemello device to meet the aforementioned limitation. Specifically, it is noted that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. (See In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)). It is submitted that one skilled in the art would not

Attorney Docket No.: 10139 - 04101

have been motivated to modify the Chemello device to place the lip 91 in contact with the greater trochanter, as doing so would provide no benefit thereto and would undermine a goal of the invention -- i.e., facilitating removal nail from the bone.

For these additional reasons, it is submitted that Chemello fails to teach or suggest the limitations of claim 1. Because claims 7, 9 and 13 depend from, and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 21 recites limitations substantially similar to those of claim 1 including a bone fixation device comprising "an intramedullary pin having a longitudinal axis, a proximal end, and a distal tip configured and dimensioned for insertion into a medullary canal of a bone, the intramedullary pin having a total length with proximal and distal halves, and the proximal half of the intramedullary pin includes at least one borehole passing through the intramedullary pin transverse to the longitudinal axis, the at least one borehole defining a transverse borehole axis; a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter; wherein the length of the plate ends proximally above the borehole in the intramedullary pin; and wherein the bone plate includes an angled tab with a center of gravity, the angled tab configured and dimensioned such that a first plane defined by the center of gravity and the longitudinal axis intersects a second plane defined by the transverse borehole axis and the longitudinal axis at an angle β of between 0° and $+100^{\circ}$ degrees." (Emphasis Added). It is therefore submitted that claim 21 is allowable for at least the same reasons noted above with regard to claim 1.

II. The Rejection of Claims 6 and 16 Under 35 U.S.C. § 103(a) as Obvious over Chemello Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 6 and 16 were rejected under 35 U.S.C. 103(a) as unpatentable over Chemello. (See 9/17/07 Office Action, p. 4).

B. Chemello Does not Show or Suggest an Angled Tab as Recited in Claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection under Chemello. Claims 6 and 16 depend from and therefore include all the limitations

Attorney Docket No.: 10139 - 04101

of independent claim 1. As discussed above, Chemello fails to teach or suggest "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter" or "an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100," as recited in claim 1. As also noted above, modifying the Chemello device to overcome these limitations is not allowable. Accordingly, because claims 6 and 16 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable for the same reasons. Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claims 6 and 16.

III. The Rejection of Claims 1, 4 - 8, 13 and 16 Under 35 U.S.C. § 103(a) as Obvious over Stedtfeld in view of Chemello Should be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claims 1, 4 - 8, 13 and 16 were rejected under 35 U.S.C. 103(a) as obvious over Stedtfeld in view of Chemello. (See 9/17/07 Office Action, pp. 4 - 7). The Examiner stated that Stedtfield discloses the device as claimed but fails to disclose a bone plate attached to the proximal end of the intramedullary pin. The Examiner references Chemello to overcome this deficiency. (Id.) In the Advisory Action dated 12/3/07, however, the Examiner states that "Chemello is not being used to teach the bone plate" and that "[t]he examiner believes that Stedtfeld discloses a bone plate capable of performing the functional limitations of the claims." (See 12/3/07 Advisory Action, p. 2).

B. Stedtfeld and Chemello Do not Disclose or Suggest an Angled Tab or Bone Plate as Recited in Claim 1

Initially, it is noted that the Examiner's notes in the Advisory Action contradict those made in the Final Office Action. Accordingly, Appellants have addressed both arguments herein.

With respect to the Final Office Action, it is submitted that the Examiner is correct in stating that Stedtfeld fails to disclose a bone plate attached to the proximal end of the

Attorney Docket No.: 10139 - 04101

intramedullary element much less "an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle $\hat{\beta}$ is between 0° and +100° or between 0° and -100°," as recited in claim 1. However, as noted above with regard to the 35 U.S.C. § 102(b) rejection, Chemello also fails to cure this deficiency. Accordingly, it is submitted that Stedtfeld and Chemello, taken either alone or in combination, neither teach nor suggest "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter" or "an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100°," as recited in claim 1. Accordingly, it is respectfully submitted that claim 1 is allowable over Stedtfeld and Chemello taken either alone or separately for the same reasons stated above in regard to the anticipation rejection. Since claims 4 - 8, 13 and 16 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

With respect to the Examiner's arguments presented in the Advisory Action, it is submitted that Stedtfeld does not teach or suggest a bone plate therein. Stedtfeld makes no mention of a bone plate whatsoever and is limited solely to a locking nail 1 comprising a sleeve 17 and pin 24. (See Stedtfeld, Abstract, ¶ [0031]; Fig. 1). It is unclear what reference the Examiner has used to assert that Stedtfeld teaches a bone plate as no element of the kind is disclosed therein. In any case, it is submitted that any new application of these references would constitute a new grounds of rejection removing the finality of the rejection. Accordingly, it is submitted that neither Stedtfeld nor Chemello teaches "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter," as recited in claim 1. In any case, it is respectfully submitted that claim 1 and its dependent claims 4 - 8, 13 and 16 are allowable over Stedtfeld and Chemello for the reasons discussed above.

Attorney Docket No.: 10139 - 04101

IV. The Rejection of Claim 14 Under 35 U.S.C. § 103(a) as Obvious over Stedtfeld in view of Chemello in further view of Pennig Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claim 14 was rejected under 35 U.S.C. 103(a) as obvious over Stedtfeld in view of Chemello in further view of Pennig. (See 9/17/07 Office Action, p. 7).

B. Neither Stedtfeld nor Chemello nor Pennig Discloses or Suggests an Angled Tab or a Bone Plate as Recited in Claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Stedtfeld and Chemello. Claim 14 depends from and therefore includes all the limitations of independent claim 1. As discussed above, Stedtfeld and Chemello do not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable over Stedtfeld and Chemello, either alone or in combination. Pennig does not cure the deficiencies of Stedtfeld and Chemello noted above. Accordingly, it is respectfully submitted that claim 14 is allowable for the same reasons stated in regard to claim 1.

V. The Rejection of Claim 18 Under 35 U.S.C. § 103(a) as Obvious over Stedtfeld in view of Chemello in further view of Seidel Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claim 18 was rejected under 35 U.S.C. 103(a) as obvious over Stedtfeld in view of Chemello in further view of Seidel. (See 9/17/07 Office Action, pp. 7 - 8).

B. Neither Stedtfeld nor Chemello nor Seidel Discloses or Suggests an Angled Tab or a Bone Plate as Recited in Claim 18

Claim 18 recites limitations substantially similar to those of claim 1, including "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate including an angled tab with a pair of petals extending toward the distal end of the intramedullary pin and adapted to

Attorney Docket No.: 10139 - 04101

lie in contact with the greater trochanter" and an angled tab "configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100°." Accordingly, it is submitted that Stedtfeld and Chemello fail to show or suggest the recited arrangement. It is further submitted that Seidel fails to cure the above noted deficiencies of Chemello and Stedtfeld and that claim 18 is allowable for the same reasons noted above in regard to claim 1:

VI. The Rejection of Claims 17, 19 and 20 Under 35 U.S.C. § 103(a) as Obvious over Stedtfeld in view of Chemello in further view of Seidel in further view of Pennig Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 17, 19 and 20 were rejected under 35 U.S.C. 103(a) as obvious over Stedtfeld in view of Chemello in further view of Seidel in further view of Pennig. (See 9/17/07 Office Action, p. 8).

B. Neither Stedtfeld, Chemello, Seidel nor Pennig Discloses or Suggests either an Angled Tab or a Bone Plate as Recited in Claims 1 and 18

Claims 1 and 18 have been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Stedtfeld and Chemello. Claim 17 and 19 - 20 depend from and therefore includes all the limitations of independent claims 1 and 18. As discussed above, Stedtfeld and Chemello do not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable over Stedtfeld and Chemello, either alone or in combination. Seidel and Pennig do not cure the deficiencies of Stedtfeld and Chemello noted above. Accordingly, it is respectfully submitted that claims 1 and 18 are allowable over Stedtfeld, Chemello, Seidel and Pennig. It is therefore submitted that claims 17 and 19 - 20 are allowable for the same reasons stated in regard to claims 1 and 18.

Attorney Docket No.: 10139 - 04101

VII. The Rejection of Claims 1, 9, 11 and 12 as Obvious over Aginsky in view of Chemello Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 9, 11 and 12 were rejected under 35 U.S.C. 103(a) as obvious over Aginsky in view of Chemello. (See 9/17/07 Office Action, pp. 8 - 10).

B. Neither Aginsky nor Chemello Discloses or Suggests Either an Angled Tab or a Bone Plate as Recited in Claim 1

Aginsky purports to show a nail with a tubular sheath intended to be traversed therethrough a fractured thigh-bone. (See Aginsky, col. 3, ll. 41 - 56). Aginsky fails to teach or suggest "a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter; wherein the length of the plate ends proximally above the borehole in the intramedullary pin; and wherein the bone plate includes an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle \beta relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100°", as recited in claim 1. The Examiner asserts that this deficiency is cured by Chemello. However, as described above, Chemello neither shows nor suggests these claim limitations and Aginsky fails to cure this deficiency and, for at least this reason, it is respectfully submitted that claim 1 is allowable over Chemello and Aginsky taken either alone or in combination. Since claims 9, 11 and 12 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Group Art Unit: 3733

Attorney Docket No.: 10139 - 04101

8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 103(a) and indicate that claims 1 - 23 are allowable.

Respectfully submitted,

Date: March 26, 2008

Oleg F. Kaplun (Reg. No. 45,55

Fay Kaplun & Marcin, LL, 150 Broadway, Suite 702 New York, NY 10038 Tel: (212) 619-6000 Fax: (212) 619-0276

Attorney Docket No.: 10139 - 04101

CLAIMS APPENDIX

1. (Previously Presented) A bone fixation device comprising:

an intramedullary pin having a longitudinal axis, a proximal end, and a distal tip configured and dimensioned for insertion into a medullary canal of a bone, the intramedullary pin having a total length with proximal and distal halves, and the proximal half of the intramedullary pin includes at least one borehole passing through the intramedullary pin transverse to the longitudinal axis, the at least one borehole defining a transverse borehole axis;

a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter;

wherein the length of the plate ends proximally above the borehole in the intramedullary pin; and

wherein the bone plate includes an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100°.

- 2. (Canceled).
- 3. (Canceled).
- 4. (Previously Presented) The device of claim 1, wherein the distal half of the intramedullary pin further includes a transverse borehole passing through it for accommodating a locking screw.
- 5. (Previously Presented) The device of claim 1, wherein the intramedullary pin, is provided with at least two transverse grooves in its distal half.

Group Art Unit: 3733

Attorney Docket No.: 10139 - 04101

6. (Previously Presented) The device of claim 1, wherein the bone plate and the intramedullary pin are a single piece.

- 7. (Previously Presented) The device of claim 1, wherein angle β is between +40° and +50°.
- 8. (Previously Presented) The device of claim 1, wherein the proximal half of the intramedullary pin has a second transverse borehole, which passes through it for accommodating a second hip screw.
- 9. (Previously Presented) The device of claim 1, wherein the bone plate has a circular borehole and the proximal rear end of the intramedullary pin has a cylindrical elevation corresponding thereto, so that the bone plate may be disposed about this elevation.
- 10. (Previously Presented) The device of claim 1, wherein the bone plate has a cam, which can be lowered into a depression, provided at the proximal end at the intramedullary pin, so that the bone plate can be connected with the intramedullary pin in a defined relative position and secured against rotation.
- 11. (Previously Presented) The device of claim 9, wherein the cylindrical elevation at the proximal end of the intramedullary pin has an external thread.
- 12. (Previously Presented) The device of claim 11, further comprising a nut with an internal thread corresponding to the external thread.
- 13. (Previously Presented) The device of claim 1, wherein the tab, viewed parallel to the longitudinal axis, extends around the intramedullary pin at an angle α , the angle α being between 10° and 200°.
- 14. (Previously Presented) The device of claim 1, wherein the bone plate has at least one perforation.
- 15. (Previously Presented) The device of claim 10, wherein the cylindrical elevation at the

Group Art Unit: 3733 Attorney Docket No.: 10139 - 04101

proximal rear end of the intramedullary pin has an external thread.

16. (Previously Presented) The device of claim 1, wherein angle β is between -40° and -50°.

17. (Previously Presented) The device of claim 1, wherein the bone plate includes a pair of petals having at least two perforations.

18. (Previously Presented) A bone fixation device comprising:

an intramedullary pin having a longitudinal axis, a proximal end, and a distal end configured and dimensioned for insertion into a medullary canal of a bone, the intramedullary pin having a total length with proximal and distal halves, the proximal half of the intramedullary pin including at least one borehole passing through the intramedullary pin transverse to the longitudinal axis, the at least one borehole defining a transverse borehole axis;

a bone plate disposed at the proximal end of the intramedullary pin, the bone plate including an angled tab with a pair of petals extending toward the distal end of the intramedullary pin and adapted to lie in contact with the greater trochanter;

wherein the angled tab does not extend past the borehole in the intramedullary pin; and wherein the angled tab is configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100°.

- 19. (Previously Presented) The device of claim 18, wherein the angled tab includes a plurality of perforations.
- 20. (Previously Presented) The device of claim 18, wherein the angled tab extends around the intramedullary pin over an angle of between 10° and 200° relative to the longitudinal axis.

Group Art Unit: 3733 Attorney Docket No.: 10139 - 04101

21. (Previously Presented) A bone fixation device comprising:

an intramedullary pin having a longitudinal axis, a proximal end, and a distal tip configured and dimensioned for insertion into a medullary canal of a bone, the intramedullary pin having a total length with proximal and distal halves, and the proximal half of the intramedullary pin includes at least one borehole passing through the intramedullary pin transverse to the longitudinal axis, the at least one borehole defining a transverse borehole axis;

a bone plate disposed at the proximal end of the intramedullary pin, the bone plate having a length extending toward the distal tip of the intramedullary pin and adapted to lie in contact with the greater trochanter;

wherein the length of the plate ends proximally above the borehole in the intramedullary pin; and

wherein the bone plate includes an angled tab with a center of gravity, the angled tab configured and dimensioned such that a first plane defined by the center of gravity and the longitudinal axis intersects a second plane defined by the transverse borehole axis and the longitudinal axis at an angle β of between 0° and +100° degrees.

No.: 10/530,087 Group Art Unit: 3733 Attorney Docket No.: 10139 - 04101

EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

No.: 10/530,087 Group Art Unit: 3733 Attorney Docket No.: 10139 - 04101

RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.